

REMARKS

Claims 1-77 and 80 are pending in this application. The claims are not amended, however, pending claims are provided herewith for the convenience of the Examiner. The Office Action is discussed below:

Obviousness Rejections:

On pages 2-5 of the Office Action, this Examiner rejects claims 1-2, 5-19, 21-35, 38-40, and 77 allegedly as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904) and Higgins (US 5,753,182).

On page 6 of the Office Action, the Examiner rejects claim 20 under 35 U.S.C. 103(a) as allegedly being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904), and Higgins (US, 5753182), and in further view of Parth *et al.* (2002).

On pages 6-7 of the Office Action, the Examiner also rejects claims 3-4 and 36-37 allegedly as being unpatentable over Lidgren *et al.* (US ,6,448,315) in view of Hahn (US Patent No. 5,827,904), and Higgins (US 5,753,182), and in further view of Burstein *et al.* (US ,6,620,198).

On pages 7-10 of the Office Action, the Examiner also rejects claims 41, 42, 45-49, 52-55, 57, 59-62, and 64-72 allegedly as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904).

On pages 10-11 of the Office Action, the Examiner also rejects claims 43-44, 50-51, 56, 58, 63 and 73-75 allegedly as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904) and in further view of Burstein *et al.* (US 6,620,198).

On pages 11-12 of the Office Action, the Examiner also rejects claims 76 and 80 allegedly as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904) and in further view of Burstein *et al.* (US 6,620,198) and Ylanen *et al.* (US 6,517,857).

Apparently, this Examiner has maintained the obviousness rejections of the claims and alleged as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904) and further in view of Parth *et al.* (2002), and/or Burstein *et al.*

(US 6,629,198), and/or Ylanen *et al.* (US 6,517,857) and the newly added a reference Higgins (US 5,753,182).

Applicants respectfully disagree with the Examiner, traverse the rejections and note that the Examiner has failed to distinguish the claimed invention over the art. Applicants indicate that the Examiner has not addressed the unexpected results that the instant invention provides, for example, higher crosslink density and hence better wear resistance that is obtained in accordance of the claimed invention. Examiner has wrongfully referred to Higgins (US 5,753,182) disclosure for diffusion of hydrogen gas into irradiated UHMWPE to extinguish free radicals. Applicants point out that vitamin-E or any anti-oxidant does not extinguish the free radicals but rather prevent the reaction of the free radicals with oxygen. Therefore, the newly cited reference Higgins (US 5,753,182) is not applicable to the claimed method of making oxidation and wear resistant materials. Applicants further provide the following response:

Response to Arguments:

On pages 12-15 of the Office Action, in response to the arguments, filed on March 12, 2007, the Examiner states that the process of Lidgren in view of Hahn teaches soaking a consolidated polymeric material in an antioxidant solution and referred that the laws of diffusion apply such that the antioxidant solution diffuses into the consolidated polymeric material. The Examiner also refers to Fick's Laws on diffusion and believes that a gradient of antioxidant is formed in the consolidated polymeric material because the consolidated polymeric material is soaked in the antioxidant solution.

In response, applicants reiterate that the art of record does not teach or suggest, either alone or in combination, the formation of a "gradient of antioxidant in the consolidated polymeric material" (see pages 13-14 of the response filed on September 29, 2006). Further, applicants specifically mention that Lidgren does not teach a gradient of antioxidant because Lidgren requires mixing of UHMWPE powder/particles with an antioxidant prior to consolidation (see page 14 of the response filed on September 29, 2006). As applicants teach, consolidation allows for the gradient, and would be required before any irradiation step.

According to the Examiner, the unexpected result that appears to be asserted is that doping of a consolidated part provides improved wear resistance over doping prior

to irradiation because doping prior to irradiation interferes with the process of cross-linking which occurs during irradiation (refers to page 13 of the March 12, 2007 reply and page 4, paragraph 5 of the declaration under 37 CFR 1.132 filed on April 21, 2006). The Examiner stated previously (page 10 of the action mailed 30 May 2006) that objective evidence of the new or unexpected results should be commensurate in scope with the claims which the evidence is offered to support. In this case, according to the Examiner, various orders of steps are sought (refers to page 10 of the May 30, 2006 action for a description), and the assertions of criticality or unexpected results appear to support only some of the independent claims where it is claimed that irradiation precedes doping (refers to page 10 of the May 30, 2006 non-final rejection).

Applicants respectfully disagree with the Examiner and refer to the specification 'Background' section (see specification, for example, page 2, lines 3-22; page 18, lines 12-19) to show that the unexpected results and superior product are a result of the instant invention and include, for example, improved wear resistance.

Applicants also mention that the specification distinguished the cited references Lidgren *et al.* (US 6,448,315) and Hahn (US 5,827,904) from the instantly claimed invention. More specifically, Lidgren and Hahn teach mixing of polyethylene powder with antioxidants, followed by consolidating the antioxidant-powder mix to obtain oxidation resistant polyethylene. Mixing of the resin powder, flakes, or particles with vitamin E and consolidation thereafter result in changes in physical properties of polymeric material. In addition, the addition of the antioxidant to the UHMWPE prior to irradiation can inhibit cross-linking of the UHMWPE during irradiation (see specification, for example, page 2, lines 11-22).

Just as important, Lidgren and Hahn reduce potency of the antioxidants because the UHMWPE is doped before irradiation, and as a result requires more antioxidants in order to ensure long-term stability of the UHMWPE. But, pre-irradiation blending of the UHMWPE with high amount of vitamin E further reduces the cross-linking efficiency of the host polymer. Therefore, it becomes very difficult to develop a balance in the concentration of vitamin E in order to ensure long-term stability and high cross-linking efficiency of the UHMWPE without unduly compromising the overall antioxidant potency.

Applicants refer to the specification concerning, for example, doping with vitamin E subsequent to consolidation, which avoids the exposure of vitamin E to high temperatures and pressures, which thereby prevents the discoloration of the polymeric material. Post-irradiation doping also avoids the adverse effects of the cross-linking irradiation. Moreover, applicants' approach avoids the thermal effects that would otherwise reduce the effectiveness of the antioxidant (for example, the potency of vitamin E) in protecting the finished polymeric material against oxidation.

The thermal effects of blending Vitamin E at the powder stage are a result of the very high temperatures employed, and adversely affect the potency of the antioxidant. In contrast, with lower temperatures (such as less than the melting point of polyethylene) the decline in the potency of the antioxidant is significantly less. Therefore, applicants used lower temperatures during doping with vitamin E. (see. e.g., specification, page 18, lines 12-19 and Example 22), and permits the invention to avoid the difficult balance that the prior art requires.

With regard to the assertions of criticality of irradiation and subsequent doping with vitamin E, the Examiner asserts the new reference Higgins (US 5,753,182) and believes that Higgins teaches irradiation of a consolidated polymeric material (refers to 3:1-37), and then to subsequently dope the medical implant with the flammable gas hydrogen in order to extinguish free radicals (refers to col. 3:25-45). Applicants disagree with the Examiner and mention that the Examiner has wrongfully equated that doping with explosive hydrogen gas to extinguish free radicals is a process similar to preventing the formation of peroxy radicals by vitamin E doping, which is a safe, inflammable, and biocompatible approach. In particular, the Examiner refers that Higgins teaches that irradiation produces free radicals in polymeric implants (refers to col. 2:14-35), and that free radicals crosslink with other local polymer chains (refers to col. 1:55-57), leading to an improvement in the abrasion resistance (refers to col. 1:58-63), but that free radicals react with oxygen *in vivo*, producing a troublesome result (refers to col. 2:6-13). The Examiner reasoned that while Lidgren teaches that free radicals are extinguished by doping with vitamin E and then irradiating, Higgins teaches that a desirable result is provided by first irradiating and cross-linking, and then subsequently extinguishing free radicals by doping the polymeric material with explosive hydrogen gas. Again, applicants disagree with the Examiner and mention that the Examiner has equated doping with pressurized and highly dangerous

flammable hydrogen gas as equivalent to doping with a safe and biocompatible antioxidant like vitamin E.

Applicants also indicate that Higgins disclosure relates to post sterilization reduction of free radicals in polyethylene that are subject to low dose irradiation (as high as 10.0 Mrad) for the sterilization purpose (see Higgins, for example, col. 2:20-31; col. 2:65-67; and col. 3:24-44). Therefore, the Examiner's judgment on obviousness is based upon proscribed hindsight reasoning and the knowledge gleaned from the instant invention.

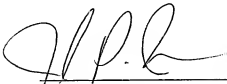
Finally, on page 15 of the Office Action the Examiner refers that it is suggested by Hahn that the step of doping with an antioxidant can be performed at various points in the fabrication process in order to reduce free radicals. However, the Examiner has not indicated where in the Hahn such an alleged suggestion can be found.

In view of the above facts and arguments, applicants submit that the combination of the cited references does not render the claimed invention obvious. Therefore, withdrawal of the obviousness rejection is solicited.

REQUEST

Applicants submit that claims 1-77 and 80 are in condition for allowance and request consideration to that effect. The Examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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